LOUISIANA BOARD OF DRUG AND DEVICE DISTRIBUTORS

12091 Bricksome Avenue, Suite B Baton Rouge, LA 70816
(225) 295-8567 Fax (225) 295-8568 Lsbwdd@Lsbwdd.org www.Lsbwdd.org

ANNUAL RENEWAL FOR LICENSURE AS A DISTRIBUTOR OF LEGEND DRUGS OR DEVICES

LICENSE RENEWAL application must be submitted annually for the Distributor of Legend Drug or Device license to sale or facilitate delivery of legend drugs or devices in and/or into the State of Louisiana as provided by LA R.S. 37:3461 through R.S. 37:3482, as amended**.** Licenses expire on December 31st of each calendar year. Licenses shall be renewed by submitting a renewal application and the renewal fee between October 1 and December 31 of each year; online renewal submission with electronic fee payment is now available on the Board's website. A reinstatement fee must be paid in addition to the renewal fee for renewals not received at the Board office postmarked by or completed by December 31st of each year.

Licenses are not transferable with regards to location changes or changes of ownership; please utilize the Application for License form to apply for a new license (location change or change of ownership). The license application form is available on the Board website or by contacting the Board office. New licenses issued by the Board shall expire on December 31 of the calendar year issued. If there has been a change in ownership or location, DO NOT RENEW THE CURRENT LICENSE.

Requests for voluntary cancellation of a Louisiana license must be made by the licensee in writing and must include the date the cancellation is effective and the reason for the voluntary cancellation (non-renewal) of the license.

Current license information on the pre-printed renewal form provided must be reviewed for accuracy and/or corrected (DO NOT white-out or remove current information; utilize space provided in the "CORRECTIONS:" column or attach corrected/updated information on separate sheet); each line must be checked off as reviewed to complete the form. Renewal form must be signed by an authorized representative of the licensee, and submitted to the Board at the address above, along with all required documentation and the appropriate fee(s) (payable to the *Louisiana Board of Drug or Device Distributors*). Renewal fees for multiple renewal applications may be paid on one check, money order, or cashier's check but each renewal application form must be prepared complete including copies of all required attachments.

INSTRUCTIONS:

1) Do not write in the gray shaded areas – for BOARD USE ONLY.
2) The pre-printed renewal form provided is for annual license renewal. If there has been a location change or change of ownership, discard the renewal form and utilize the Application for License form to apply for a new license for location change or change of ownership. The application form is available on the Board website or by contacting the Board office.
   a) Renewal - for licensees applying for annual renewal of license – fee is $300.
      i) Reinstatement – for licensees whose license had expired; was submitted or not completed by December 31 – fee is $300 (both fees are due).
3) All items on the renewal application form must be verified for accuracy and provided or corrected where needed. DO NOT white-out or remove current information; use the "CORRECTIONS:" spaces provided or attach corrections/updates on separate sheet. If an item does not apply, indicate or mark "Not applicable", "(NA)". Each line must be checked off as reviewed to complete the form.
   a) Verify the name of the company for the license issued. Note: Changes in company name not associated with a change in ownership requires submission of the Request for Name Change form – the name change fee is not required when name change request is submitted with the license renewal.
   b) Verify or provide any "doing business as" (dba) or trade names used by the licensee. Please note that a separate license is required for each division, subdivision, subsidiary, or affiliate company owned by the same business entity or parent company when distribution operations are conducted independently by the division, subdivision, subsidiary, or affiliate company and/or the division, subdivision, subsidiary, or affiliate company is independently incorporated.
   c) Verify the distribution center address, city, state, and zip code. Note: Change in location requires application for new license.
   d) Verify the use of a third-party logistics provider (3PLP) (as defined in number 3)f)v. of these instructions), when applicable.
      i) Verify the use of more than one 3PLP facility location used for distribution of the licensee's legend drugs or devices; any additional 3PLPs being utilized will be listed by their Louisiana license number.
   e) Verify the type of business conducted that is currently on file.
      i) Sales – having ownership and engaged in the sale of legend drugs or devices in or into Louisiana.
      ii) Facilitates Delivery – engaged in the physical delivery of legend drugs or devices in or into Louisiana.
   f) Verify type of distributor (sub-type) that is current on file
      i) Manufacturer – (a) any person who manufacturers drugs or devices including a labeler or distributor; (b) any person who prepares drugs in dosage form by mixing, compounding, encapsulating, entableting, or by other process; (c) any person who manufacturers, assembles, processes, or modifies devices; (d) a person who holds an approved new drug application under FDA or hold a biologics license issued by FDA or the person who manufacturers the product; (e) an affiliate of a person thus described as (a), (b), (c), or (d) that receives the drug or device directly from the person thus described; or (f) a co-licensed partner of the person thus described as (a), (b), (c), or (d) that obtains the drug or device directly from a person thus described.
      ii) Re-packager – a person who owns or operates an establishment that repacks and relabels a drug, device, or package thereof for further sale or distribution without a further transaction.
      iii) Broker – any person participating in drug or device distribution that buys or sells the drug or device but does not take physical possession such that it is sold to the broker and delivered to a third party.
      Agent – any person authorized by another person called the *principal* to act for him or on his behalf in drug or device distribution and who may or may not take physical possession such that the drug or device is sold to the agent and may be delivered to a third party.

iv) Freight Forwarder – any person participating in drug or device distribution that acts as the agent for the distribution of a drug or device and does or does not take physical possession such that it is sold to the broker and delivered to a third party.
v) Third-Party Logistic Provider (3PLP) – a person that provides or coordinates warehousing, facilitation of delivery, or other logistic services for a drugs or device in interstate and intrastate commerce on behalf of the owner of a drug or device but does not take ownership of the drug or device nor have responsibility to direct the sale or disposition of the drug or device.
vi) Jobber – any person who purchases drugs or devices usually in bulk to sell to another person in the drug or device distribution industry.
Private Labeler – any person that packages and/or manufactures and packages a drug or device that bears the name of the distributor along with the distributor's national drug code number and lot number.
vii) Nuclear Pharmacy – any person that compounds radioactive materials for use in nuclear medicine procedures.
viii) Ship Chandlers – any person that provides legend drugs or devices to seafaring ships.
ix) Reverse Distributors – any person that receives legend drugs or devices for the purpose of arranging the return and/or the destruction of the legend drugs or devices.
x) Retail Pharmacy Warehouse – any person that acts as a central warehouse and performs intra-company sales or transfers to retail pharmacies under common ownership.
xi) Pharmacy – any place where drugs are dispensed and pharmacy primary care is provided.
xii) Wholesale Distributor – a person engaged in distribution of drugs or devices to persons other than the consumer or patient except as exempted in the standards of the federal DSCS Act as the act pertains to wholesale distribution.
xiii) Outsourcing Facility – a facility that engages in compounding of (non-patient specific) sterile drugs.

g) Verify the type of business as currently on file.
h) Verify the type of ownership as currently on file; list of owners.
   i) Individual(s) – list of individual owners possessing greater than 10% interest in the licensee.
   ii) Corporately Owned – the name of corporate parent company.
   iii) Publicly Traded – trading symbol
   iv) Privately Held – the name(s) of trusts, holding companies, financial corps, investment groups, closed corporations, etc.
i) Verify or provide the state of incorporation (or formation).
j) Verify the manner of distribution that is currently on file.
k) Verify the type of product distributed as currently on file.
l) Out-of-State Facilities must have on file at all times a copy of their current home state distributor license as issued by the regulatory agency in the state in which the licensee is located (or manufacturer license or FDA registration, when applicable).
   i) Verify the state license number and expiration date that is currently on file. If the out-of-state license has expired, provide a copy of the current (renewed) license.
   ii) An "X" mark indicates if the state in which the licensee is located does not require the licensee to license and the licensee utilizes a 3PLP for distribution – the 3PLP's home state license and expiration date will be noted; if expired, provide a copy of the 3PLP's current home state license.
   iii) An "X" mark indicates if the licensee is a legend device only distributor whose state in which it is located does not require the licensee to license; an FDA establishment registration may be on file; if expired, provide a copy of the current FDA registration.
m) If the licensee is distributing controlled substances, the licensee should provide their federal DEA number and a Louisiana Controlled Dangerous Substance (CDS) registration number (as issued through the Louisiana Board of Pharmacy, CDS Program). Verify or provide a federal DEA number and LA State Controlled Substance Number, if applicable.
n) Verify or provide list of executive/corporate officers and the board of director (when applicable). The date for the last list submitted is provided
o) The licensee must submit a list of every state or territory where the licensee facility holds a current license as a wholesale distributor of legend drugs or devices (no license copies are required except where required above in item "l)").
   i) An "X" mark will indicate if licensee is not licensed in any other states.
   ii) If there is a list of other state/territory licensed on file with the Board office and the information has change within past year, attached a revised listing. The date for the last list submitted is provided.
p) Verify the contact person for the licensee's distribution facility <u>OR</u> the licensee's contact person for management of the legend drug or device product owned by the licensee as distributed by a 3PLP, if applicable; verify, correct, or provide email address, telephone number, and fax number for the facility contact person.
q) Verify the contact person for licensing and regulatory affairs; verify, correct, or provide email address, telephone number, and fax number for the regulatory contact person.
r) Verify the Designated Responsible Party (DRP); verify, correct, or provide email address, telephone number, and fax number. <u>Note</u>: Changes of DRP require submission of a DRP Qualification Review form; form available on Board's website.
s) Verify the licensee's mailing address, city, state, and zip code.
t) Verify the business address, city, state and zip code for the licensee company – *this would be the address for the location at which product title is held and/or from which sales and/or invoicing is done, moneys collected*.
   i) If applicable, when the business address is different from distribution center location and the business location also physically distributes legend drugs/devices, the separate Louisiana license for the business address location will be noted. Please note that all locations that wholesale/ distribute legend drugs/ devices must be separately licensed.
u) Disciplinary Actions –
   i) Complete all questions regarding disciplinary action taken against the licensed facility only. If disciplinary action documentation has previously been submitted to the Board, check the appropriate box. If infraction occurred since last renewal, attach an explanation and any pertinent documentation related to the matter.
v) Application Certification –
   i) After completion of the form, an authorized representative of the licensee must read the certification and sign and date the application in acceptance.